UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

KRANTHI GORLAMARI, Individually and On Behalf of All Others Similarly Situated,

Plaintiff,

v.

VERRICA PHARMACEUTICALS, INC., TED WHITE, P. TERENCE KOHLER JR. and A. BRIAN DAVIS,

Defendants.

Case No. 2:22-cv-02226-MSG

AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

JURY TRIAL DEMANDED

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Lead Plaintiff Kranthi Gorlamari ("Plaintiff"), individually and on behalf of all others similarly situated, by and through his attorneys, hereby brings this Amended Class Action Complaint ("Complaint") against Verrica Pharmaceuticals, Inc. ("Verrica" or the "Company"), Ted White ("White"), P. Terence Kohler Jr. ("Kohler"), and A. Brian Davis ("Davis") (together, "Defendants"). The allegations herein are based on Plaintiff's personal knowledge as to his own acts and on information and belief as to all other matters, such information and belief having been informed by the investigation conducted by and under the supervision of Lead Counsel, which includes a review of: U.S. Securities and Exchange Commission ("SEC") filings by Verrica; securities analysts' reports about the Company; press releases and other public statements issued by and disseminated by the Company; media reports about the Company; and interviews of former employees of Verrica and other persons with knowledge of the matters alleged herein. Lead Counsel's investigation into the matters alleged herein is ongoing and many relevant facts are known only to, or are exclusively within the custody or control of, the Defendants. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION AND OVERVIEW

1. This is a class action on behalf of persons and entities that purchased or otherwise acquired Verrica securities between May 19, 2021 and May 24, 2022, inclusive (the "Class Period"). Plaintiff pursues claims against the Defendants under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Verrica is a dermatology therapeutics company which develops medications for skin diseases that require medical treatment. Its lead product candidate, VP-102, is a drug device combination of Verrica's topical solution, cantharidin, administered through a single-use precision applicator. The Company is developing VP-102 for the treatment of: molluscum

contagiosum (generally referred herein as "molluscum"), an infection most common in children that is caused by a poxvirus that results in a skin disease with lesions; external genital warts; and common warts.

3. Throughout the Class Period, Defendants misleadingly misled the market as to material and significant risks relating to Verrica obtaining regulatory approval of VP-102 for molluscum. Verrica's path towards obtaining regulatory approval began prior to the Class Period, when in September 2019 the Company submitted a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") seeking regulatory approval of VP-102 for the treatment of molluscum. In July 2020, Verrica received a Complete Response Letter ("CRL") from the FDA. In response, Verrica changed its packaging to address the FDA's concerns and resubmitted its NDA to the FDA in December 2020.

4. As the Class Period began, the time for the FDA's response to this resubmitted NDA drew close. On April 13, 2021, Verrica's CEO, Defendant White, told investors and analysts during a healthcare conference that as part of the FDA's review of the resubmitted NDA, the FDA planned to inspect two facilities Verrica contracted with to manufacture VP-102. The FDA requires inspections of manufacturing facilities to assess for compliance with Current Good Manufacturing Practices ("cGMP"), regulations that contain minimum requirements for manufacturers and facilities concerning all aspects of production. Thus, the status and results of these FDA facility inspections were top mind for investors and analysts as the Class Period began.

5. On the first day of the Class Period, during the RBC Capital Markets Global Healthcare Conference held on May 19, 2021, Defendant White was asked for an update on the FDA inspections of Verrica's contract manufacturing facilities. White responded that "we fully

anticipate that we'll have our inspections take place according to plan, and we have not been notified otherwise." On May 28, 2021, Verrica announced that the FDA had extended the review period for the NDA by three months. Within that announcement, Defendant White was quoted as saying: "Importantly, the FDA has recently completed one of the two pre-approval inspections required for approval."

6. On September 20, 2021, after the market closed, Verrica announced receipt of a second CRL due to deficiencies at a facility of Verrica's contract manufacturer, Sterling Pharmaceuticals Services, LLC ("Sterling"), in connection with the Company's NDA. On this news, the Company's stock price fell $1.00, or 8.3%, to close at $11.03 per share on September 21, 2021, on unusually heavy trading volume.

7. The deficiencies at Sterling stemmed from the FDA's inspection of Sterling from May 3 to 14, 2021 (the "May 2021 Sterling Inspection"), which concluded with the FDA issuing a four-item Form 483. A Form 483 documents conditions and practices discovered during an FDA inspection of drug manufacturing facilities that render the facilities out of compliance with cGMP.

8. Defendants immediately knew that the May 2021 Sterling Inspection had taken place and had concluded with the issuance of a Form 483. A former employee of Verrica ("FE"), who was interviewed as part of Lead Counsel's investigation, recalled discussing the Form 483 during a mid-May 2021 meeting, and that those present in the mid-May 2021 meeting acknowledged that receipt of the Form 483 would delay the launch of VP-102. In addition, both Verrica and Defendant White assured investors that Verrica personnel and outside consultants would be, and were, on-site during the inspection.

9. In November 2021, Verrica again resubmitted the NDA for VP-102, claiming

"[t]he resubmission addresses the successful resolution of inspection deficiencies" at Sterling.

10. Then, on May 24, 2022, after the market closed, Verrica announced receipt of a third CRL citing "deficiencies identified during a general reinspection of Sterling Pharmaceuticals Services, LLC (Sterling), the contract manufacturing organization (CMO) that manufacture's Verrica's bulk solution drug product." On this news, the Company's shares fell $3.55, or 63.8%, to close at $2.01 per share on May 25, 2022, on unusually heavy trading volume.

11. In the May 24, 2022 announcement, Defendants admitted that the FDA made clear in the September 2021 CRL that successful resolution of the identified deficiencies at Sterling was "specifically required … for approval of [Verrica's] NDA." Also in the May 24, 2022 announcement, Defendants indirectly admitted that it was not the FDA that concluded that its concerns relating to Sterling had been satisfied, but rather that Verrica was "led to believe that any concerns at Sterling had been resolved to the FDA's satisfaction" based on: (1) the FDA's classification of the May 2021 Sterling Inspection as Voluntary Action Indicated ("VAI"), which means objectionable conditions or practices were found but the agency is not prepared to take or recommend any administrative or regulatory action; and (2) rather standard language used by the FDA when they notify a facility that an inspection has been classified VAI.

12. The identified deficiencies mentioned in Verrica's May 24, 2022 announcement stemmed from the FDA's reinspection of Sterling in February 2022 (the February 2022 Sterling Inspection"). This reinspection again concluded with the FDA issuing a four-item Form 483. The February 2022 Form 483 included repeat observations—documenting that, despite Verrica's conclusion otherwise, the FDA was not satisfied that Sterling's deficiencies had been "successfully resolved." In fact, the FDA eventually issued a Warning Letter to Sterling,

explaining that "your firm has significant violations of CGMP regulations. Your firm's poor manufacturing practices are particularly concerning because many of your products[] … are ophthalmic and directed for use in young children."

13. In sum, throughout the Class Period, Defendants made materially false and/or misleading statements, and failed to disclose material adverse facts regarding the Company's path towards obtaining regulatory approval of its lead product candidate, VP-102. Specifically, Defendants knew, and failed to disclose to investors: (1) the occurrence of the FDA's May 2021 Sterling Investigation; (2) that the May 2021 Sterling Investigation concluded with the issuance of a Form 483 to Sterling; (3) that the May 2021 Sterling Inspection and observational deficiencies had not been successfully resolved; (4) that the FDA required successful resolution of the inspection deficiencies to approve Verrica's NDA for VP-102 for molluscum; (5) the occurrence of the FDA's February 2022 Sterling Investigation; (6) that the February 2022 Sterling Investigation had resulted in the issuance of a Form 483 to Sterling; and (7) that all of the foregoing presented significant risks to Verrica obtaining regulatory approval of VP-102 for molluscum.

14. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages. Accordingly, Plaintiff seeks to pursue securities fraud claims under Section 10(b) of the Exchange Act against Defendants and under Section 20(a) of the Exchange Act against each of the Individual Defendants.

II. JURISDICTION AND VENUE

15. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

17. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District. In addition, the Company's principal executive offices are located in this Judicial District.

18. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

III. PARTIES

19. Lead Plaintiff Kranthi Gorlamari, as set forth in the certification previously filed with the Court, incorporated by reference herein (Dkt. No. 5-5), purchased Verrica securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and material omissions alleged herein.

20. Defendant Verrica Pharmaceuticals Inc. is incorporated under the laws of the Delaware with its principal executive offices located at 44 West Gay Street, Suite 400, West Chester, Pennsylvania. Verrica's common stock trades on the NASDAQ exchange under the symbol "VRCA."

21. Defendant Ted White ("White") has served as Verrica's President Chief Executive Officer ("CEO") since December 2017 and has served as a member of the Board of Directors since May 2018. Previously, from 2011 to September 2017, White was the President

and General Manager at Almirall, a global pharmaceutical company with a focus on medical dermatology, and from 1989 to 2010, served in a number of roles, most recently as a Managing Director at Novartis.

22. Throughout the Class Period, White frequently spoke to investors and analysts by presenting at analyst hosted conferences. White possessed the power and authority to control the contents of the Company's public filings with the SEC. During the Class Period, White signed and certified the accuracy of Verrica's yearly report on SEC Form 10-K for the fiscal year ended December 31, 2021 and quarterly reports on SEC Form 10-Q for each of the quarterly periods ended June 30, 2021 through March 31, 2022.

23. Defendant P. Terence Kohler Jr. ("Kohler") has been the Company's Chief Financial Officer ("CFO") since July 16, 2021. Prior to joining Verrica, Kohler served in a number of senior and executive roles at Endo International PLC ("Endo") since 2015, including most recently as Vice President of Corporate Development and Treasurer from March 2020 to July 2021.

24. Kohler possessed the power and authority to control the contents of the Company's public filings with the SEC. During the Class Period, Kohler signed and certified the accuracy of Verrica's yearly report on SEC Form 10-K for the fiscal year ended December 31, 2021 and quarterly reports on SEC Form 10-Q for each of the quarterly periods ended June 30, 2021 through March 31, 2022.

25. Defendant A. Brian Davis ("Davis"), served as Verrica's Chief Financial Officer ("CFO") from October 2019 until July 16, 2021. Prior to joining the Company, Davis, was the Chief Financial Officer of Strongbridge Biopharma plc, a global commercial-stage biopharmaceutical company focused on the development and commercialization of therapies for

rare diseases, from March 2015 to September 2019. Prior to joining Strongbridge, Davis served in various financial roles in the biotechnology/biopharmaceutical industry.

26. Throughout the Class Period, Davis spoke to investors and analysts during presentations at analyst hosted conferences. Davis possessed the power and authority to control the contents of the Company's public filings with the SEC. During the Class Period, Davis, with authority from Verrica, signed a number of SEC Form 8-Ks, which announced current reports of the Company.

27. Defendants White, Kohler, and Davis are sometimes referred to herein as the "Individual Defendants."

28. The Individual Defendants, because of their high-ranking positions and direct involvement in the everyday business of the Company, possessed the power and authority to control the contents of Verrica's reports to the SEC, press releases and other public statements, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. Each defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. The Individual Defendants are liable for the false statements and omissions pleaded herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

IV. SUBSTANTIVE ALLEGATIONS

A. Background Of Verrica And Its Business

29. Verrica is a small[1] dermatological therapeutics company developing medication

[1] As of December 31, 2021, Verrica had just 38 full-time employees, up from 29 full-time

for skin diseases that require medical treatment. Since its inception in 2013, Verrica's operations have focused on its lead product candidate, VP-102.

30. As a clinical-stage company with limited operating history, Verrica has incurred significant net losses since its inception, accumulating a net deficit of $147.4 million as of March 31, 2022. Verrica has primarily funded its operations through its public offerings, raising $78.4 million in net proceeds in its June 2018 initial public offering and $28.1 million in a March 2021 follow-on public offering, as well as through private placements of convertible debt and convertible preferred stock and borrowing under a loan agreement. The Company has no products approved by the FDA for commercialization and has not yet generated revenues from product sales.

B. Verrica's Lead Product Candidate: VP-102

31. According to Verrica's 2021 annual report on Form 10-K filed with the SEC on March 2, 2022 ("2021 10-K"), Verrica has devoted substantially all its financial resources and efforts to the development of its lead product candidate, VP-102, for the treatment of molluscum. The 2021 10-K also explained that the Company's ability to generate revenues will depend heavily on VP-102's "successful development, regulatory approval and eventual commercialization[.]"

32. VP-102 is a drug-device combination of a topical solution of cantharidin,[2] a widely recognized, naturally sourced agent to treat topical dermatological conditions, administered through a single-use applicator. If approved, VP-102 will be marketed in the

employees as of December 31, 2020.

[2] Cantharidin is an odorless, colorless fatty substance, which is secreted by many species of blister beetles. Compounded cantharidin has been used for many years by dermatologists to treat molluscum, but it is not FDA-approved, could have highly variable purity, is not readily available and is often not produced in accordance with cGMPs.

United States under the conditionally accepted brand name, YCANTH.

33. The Company is developing VP-102 for the treatment of molluscum contagiosum (or molluscum), external genital warts, and common warts. According to the CDC, molluscum is an infection caused by a poxvirus, resulting in a usually benign skin disease with lesions that may appear anywhere on the body. Molluscum spreads through direct contact and is most common in children. Molluscum typically resolves in six to twelve months, but may take as long as four years.

34. In January 2019 Verrica reported positive top-line results from their Phase 3 pivotal trials, which evaluated the safety and efficacy of VP-102 for the treatment of molluscum. Verrica also announced positive topline results for its Phase 2 clinical trial of VP-102 for the treatment of external genital warts in November 2020, and, in June 2019, announced positive topline results for its Phase 2 clinical trial of VP-102 for the treatment of common warts, but based on feedback from the FDA, the Company is evaluating whether to conduct an additional Phase 2 clinical trial of VP-102 for the treatment of common warts.

C. VP-102's Potential Commercial Market

35. There are currently no products approved by the FDA for the treatment of molluscum and common warts. Similarly, there is no established standard of care for either of these diseases. For molluscum, Verrica explained that while existing therapies do exist, they are often painful and may lead to scarring, and that while compounded cantharidin has been used for many years by dermatologists to treat molluscum, it is not FDA-approved, could have highly variable purity, and is often not produced with good manufacturing policies. Similarly, in the case of warts, although over-the-counter products exist, warts tend to be highly refractory and a cause for multiple consultations. As a result, there are significantly undertreated populations in two of the largest unmet needs in dermatology.

36. VP-102 has the potential to be the first FDA-approved product for molluscum[3] and to be characterized as a new chemical entity, which provides five years of non-patent regulatory exclusivity. VP-102 also has the potential to qualify for pediatric exclusivity in common warts, which would provide for an additional six months of non-patent exclusivity.

37. Verrica estimates that approximately six million people in the United States have molluscum, that approximately one million are diagnosed annually, and that molluscum has a 5% to 11% prevalence rate in children. Accordingly, Defendants estimate that the total addressable U.S. market for molluscum is over $1 billion, and that the molluscum prevalence in the European Union is at least as high as in the United States.

38. Likewise, Verrica estimates that the total addressable U.S. market for common warts is over $1 billion with an estimated two million patient visits each year and that a total of twenty-two million in the United States have common warts. And just like for molluscum, the Company believes that the common wart patient opportunity is just as large in the European Union.

39. All considered, VP-102 offers the possibility of considerable profits to a large market. And the market recognized this opportunity. For example, on May 13, 2021, just days before the beginning of the Class Period, analysts for RBC Capital Markets initiated coverage of Verrica, rating it Outperform, Speculative Risk, with a $19 price target. Similarly, just prior to the start of the Class Period, analysts from Northland Capital Markets assigned Verrica a rating

[3] In their May 13, 2021 analyst report, RBC Capital Markets noted that the closest potential competitor is Novan Inc.'s SB206, a topical antiviral gel that is currently in development for the treatment of molluscum. As of May 2021, this product was still conducting its Phase 3 clinical trial. Novan has since reported that its Phase 3 trial demonstrated positive efficacy results and was shown to have a favorable safety profile, and on January 6, 2023, Novan announced that it had submitted an NDA for SB206 for the topical treatment of molluscum.

of Outperform with a $24 price target, Cowen and Company assigned an Outperform rating with a $25 price target, and HC Wainwright & Co. assigned a Buy rating with a $24 price target.

40. These revenues and profits, however, could not be realized without obtaining FDA approval.

D. The FDA Drug Approval Process

41. In the United States, the FDA is tasked with ensuring that drugs and devices are safe and effective for their intended uses under the Federal Food, Drug, and Cosmetic Act (the "FDCA"). 21 U.S.C. §§ 351-360.

42. Before Verrica can legally market VP-102 in the United States, it must be approved by the FDA through the New Drug Application, NDA. As Verrica stated in its 2021 10-K, the FDA process for a drug to be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND [Investigational New Drug Application], which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with good clinical practice, or GCP, requirements to establish the safety and efficacy of the proposed drug for each indication;
- submission to the FDA of an NDA together with payment of the applicable user fee;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of chemistry, manufacturing and controls testing, an FDA inspection of the manufacturing facility or facilities at which the

product is produced to assess compliance with cGMP requirements, and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;

- satisfactory completion of an FDA inspection of selected clinical sites to assure compliance with GCPs and the integrity of the clinical data; and
- FDA review and approval of the NDA.

43. Prior to the start of the Class Period, Verrica had completed its pre-clinical and clinical trials. Following successful completion of the clinical trials, the data from the preclinical and clinical trials are submitted to the FDA as part of a New Drug Application ("NDA") requesting approval to market the drug in the United States. Along with the trial data, an NDA will include the proposed labeling for the product, information relating to the product's chemistry, manufacture, controls ("CMC") data, information about the manufacturing process and facilities that will be used to ensure product quality, and other relevant information.

44. The FDA then has 60 days after the NDA is received to decide whether to accept the application for filing. In determining whether to accept an NDA for filing, the FDA only reviews for completeness rather than for its substantive content.

45. If the FDA accepts an NDA for filing, under the Prescription Drug User Fee Act ("PDUFA") guidelines, the FDA has a goal of ten months from the date of "filing" a standard NDA to review and act on the submission. During this time, the FDA reviews the NDA to determine, among others, whether the proposed product is safe and effective for its intended use, and whether the product candidate is being manufactured in accordance with Current Good Manufacturing Practices ("cGMP").

46. The cGMP regulations are detailed in Part 211 of Title 21 of the Code of Federal Regulations. The cGMP regulations for drugs contain minimum requirements for manufacturers and facilities concerning all aspects of production, including buildings and facilities,

organization and personnel, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling control, holding and distribution, laboratory controls, records and reports and returned and salvaged drug products. Detailed written procedures are essential for the quality of a finished product. A manufacturer must establish specific recordkeeping instructions demonstrating that procedures are consistently and correctly followed at each step in the manufacturing process, each time a product is made.

47. As part of the NDA review, the FDA will conduct a pre-approval inspection of the manufacturing facilities where the product is manufactured to determine whether the facilities comply with cGMPs. As Verrica admitted in its 2021 10-K, "[t]he FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications."

48. After the FDA evaluates the application, manufacturing process, and manufacturing facilities, it may issue an approval letter or a Complete Response Letter ("CRL"). An approval letter authorizes commercial marketing of the product. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. A CRL generally contains a statement of specific conditions identified by the FDA that must be met in order to approve an NDA.

E. The FDA Facility Inspection Process

49. The FDA routinely conducts inspections and assessments of regulated facilities to determine compliance with applicable laws and regulations, such as the FDCA and the regulations comprising cGMP.

50. There are four basic types of FDA manufacturing facility inspections: pre-approval inspections; post-approval inspections; routine or surveillance inspections; and for-

cause inspections, which occur in response to a specific trigger, such as a recall, outbreak, or to follow-up on previously identified problems.

51. At the conclusion of an inspection, and during a closeout meeting, the investigator will issue a form entitled "Inspectional Observations," known as FDA Form 483. A Form 483 is used by the FDA to document and communicate objectionable conditions and practices discovered during inspection of drug manufacturing facilities that render the facilities out of compliance with cGMP. According to the FDA, observations are listed on a Form 483 in order of significance by the investigator.

52. Form 483 does not, however, represent a final FDA determination regarding compliance or violation of the FDCA or its relevant regulations. Rather, Form 483, along with a more detailed Establishment Inspect Report ("EIR"), the evidence and documentation collected on-site, and any responses made by the company are all considered by the FDA in determining how to classify the inspection and what, if any, further action is appropriate.

53. The FDA classifies the inspection with one of three classifications: (1) "No Action Indicated (NAI) which means no objectionable conditions or practices were found during the inspection (or the objectionable conditions found do not justify further regulatory action)"; (2) "Voluntary Action Indicated (VAI) which means objectionable conditions or practices were found but the agency is not prepared to take or recommend any administrative or regulatory action[;]" or (3) "Official Action Indicated (OAI) which means regulatory and/or administrative actions will be recommended."[4]

54. An NAI inspection is often one where no Form 483 is issued, or if a Form 483 is

[4] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspections-database-frequently-asked-questions (last accessed January 11, 2023).

issued, later in the process the FDA determines the observations were not serious. A VAI inspection may lead to inspection follow-up or more frequent inspections.

55. In an OAI inspection, the FDA may take various advisory or administrative actions or seek judicial actions to ensure the manufacturing facilities take steps to correct the violations. These actions may include issuing a warning letter, which notifies the facility, the public, and other stakeholders about violations that the FDA has documented during its inspections.

56. The FDA's policies state that it issues warning letters only for violations of regulatory significance, including cGMP. This includes "repeat" or "recurring" observations listed on a Form 483, *i.e.*, when, on two or more successive investigations, FDA investigators observe continuing problems with the same quality system(s). Violations of regulatory significance are violations that may lead to enforcement action if not promptly and adequately corrected.

57. After FDA classification of an inspection, if the result is NAI or VAI, the manufacturing facility will receive a copy of the EIR along with a decisional letter informing the facility of the inspection classification and informing the facility that the inspection was "closed" under 21 CFR §20.64(d)(3). Under this regulation, closure means the consideration of a regulatory enforcement action for purposes of when such FDA records may or may not be withheld from the public; it is not a conclusion that any Form 483 observations have been successfully resolved.

58. If an inspection is classified OAI, a facility will not receive the EIR until the relevant compliance action has been undertaken.

F. Verrica's Troubled Path To FDA Approval Of VP-102

1. Verrica Submits Its First NDA For VP-102, Resulting In A CRL From The FDA

59. Based on the January 2019 positive top-line results from Verrica's Phase 3 clinical trials for molluscum, in September 2019, Verrica submitted an NDA to the FDA seeking regulatory approval of VP-102 for the treatment of molluscum. In November 2019, the FDA accepted the NDA for filing with a PDUFA goal date of July 13, 2020.

60. On July 14, 2020, Verrica announced that the FDA had issued a CRL regarding its NDA for VP-102. Verrica explained that according to this CRL, the FDA sought "additional information regarding certain aspects of the CMC … process for the drug/device combination, as well as Human Factors validation." Verrica further stated that it planned to request a Type A meeting with the FDA to discuss the issues described in the CRL and other matters relating to the steps required to resubmit the NDA for VP-102.[5]

61. In October 2020, a Type A meeting was held with the FDA to discuss the issued identified in the July 2020 CRL. On November 17, 2020, Verrica announced that it had received the final meeting minutes from the Company's recent Type A meeting to discuss the resubmission of its NDA for VP-102 for the treatment of molluscum, and reaffirmed its expectation to resubmit the NDA for VP-102 in the first quarter of 2021.

2. Verrica Resubmits Its NDA For VP-102 After Addressing The FDA's Concerns

62. Verrica announced on December 23, 2020 that it had resubmitted the NDA for

[5] According to the FDA, a Type A meeting is necessary for proceeding with a stalled product development program to proceed or to address an important safety issue. A Type A meeting may include a meeting requested by the product's sponsor within three months after an FDA regulatory action other than an approval and may be requested by a sponsor to gain clarity on the issues outlined in a CRL.

VP-102 for the treatment of molluscum. The Company further explained in the announcement that the NDA resubmission was based on the outcome and final minutes of the Type A meeting with the FDA, which clarified the July 2020 CRL. Also in the December 23, 2020 announcement Defendant White was quoted as saying, the "expeditious[]" resubmission "focused on the … Chemistry, Manufacturing and Controls (CMC) information as well as Human Factors validation identified by the FDA in its Complete Response Letter[.]"

63. Then, on February 17, 2021, Verrica announced that its resubmitted NDA had been accepted for filing by the FDA and that the assigned PDUFA goal date was June 23, 2021.

64. Defendant White later explained the CMC and Human Factors issues that led to the July 2020 CRL and how Verrica addressed these concerns during a number of analyst healthcare conferences. For example, during the April 13, 2021, 20th Annual Needham Healthcare Conference, Defendant White explained that "[i]n our human factor study, 3 of the 15 participants removed the cap of the applicator prior to administering the product. The FDA's concern was that the solution could inadvertently squirt out on to normal skin or into somebody's eye." To address the FDA's concerns White stated that Verrica performed a "break force ampule test to show pounds per force in order to squirt the solution out." Verrica also added shrink wrap around the cap where it meets the tube of the applicator, with instructions to not remove until the ampule is broken. The change in packaging required an additional three months of registration stability data be provided to the FDA. Verrica also was asked to provide an ampule breaker, which required a repeat of the human factors study.

3. As The Class Period Begins, Defendants Announce The FDA Will Inspect Two Of Verrica's Contract Manufacturing Facilities And That The FDA Has Extended The PDUFA Date For Its Resubmitted NDA

65. During the April 13, 2021 Needham Conference, Defendant White also explained

that based on the previous CRL, the FDA planned to inspect two facilities as part of the pre-approval manufacturing inspection for Verrica's resubmitted NDA. Defendant White continued by describing and naming the two facilities: Sterling Pharmaceutical Services, LLC ("Sterling"); and PPS, in Tennessee. Defendant White further explained that Verrica has done things to "mitigate," including mock inspections of the facilities and contracting "with some outside consultancies that have ex-FDA inspectors, such as Green Leaf, that are helping us with these upcoming inspections and will be on-site when the FDA does do their inspections."

66. On the first day of the Class period, during the May 19, 2021 RBC Capital Markets Global Healthcare Conference, White was asked for an update on the FDA inspection of these two facilities. Defendant White responded that "we fully anticipate that we'll have our inspections take place according to plan, and we have not been notified otherwise."

67. Less than two weeks later, on May 28, 2021, Verrica announced that the FDA had extended the review period by three months for the NDA for VP-102 for the treatment of molluscum, with a new PDUFA goal date of September 23, 2021. In the announcement, Defendant White was quoted as saying: "Importantly, the FDA has recently completed one of the two pre-approval inspections required for approval."

4. Verrica Receives Its Second CRL Due To Deficiencies At Sterling, One Of Verrica's Contract Manufacturing Facilities

68. On September 20, 2021, after the close of the market, Verrica announced that it had received a CRL from the FDA regarding the Company's NDA for VP-102 on September 17, 2021. In this announcement, Verrica explained that "[a]ccording to the CRL, the FDA has identified deficiencies at a facility of a contract manufacturing organization (CMO), which are not specifically related to the manufacturing of VP-102 but instead raise general quality issues at the facility." In later discussions with analysts, Verrica disclosed that the CMO at issue was the

facility near St. Louis, Missouri, *i.e.*, Sterling, which has facilities located in East Carondelet, IL and Dupo, IL, neighboring villages near St. Louis, Missouri.

69. Verrica's September 20, 2021 announcement continued:

> At no time prior to the CRL was the Company notified by the FDA of any deficiencies at the CMO related specifically to the manufacturing of VP-102 or that their general investigation of the facility would have any impact on the Company's NDA. More importantly, the FDA did not identify any clinical, safety or product specific Chemistry, Manufacturing, and Controls (CMC) deficiencies related to VP-102.
>
> The Company understands from the CMO that it has implemented corrective actions to address the Agency's concerns and the CMO has advised Verrica that it is expecting a satisfactory resolution of the facility's identified deficiencies from the FDA within the next 30 business days. During this timeframe, the Company will engage with the Agency to demonstrate that the Company's good manufacturing practices, controls and processes ensure that any deficiencies at the CMO do not impact the efficacy, safety or quality of VP-102.

70. On this news, the Company's share price fell $1.00, or 8.3%, to close at $11.03 per share on September 21, 2021, on unusually heavy trading volume.

71. Verrica further spoke with analysts after their announcements. Based on these discussions, analysts from RBC Capital, Cowen, and Jeffries noted in their September 20, 2021 reports that Verrica planned to seek a Type A meeting with the FDA to resolve and/or dispute the CRL. Analysts from RBC Capital, Cowen, and Northland Capital Markets understood that the CRL would likely push back the FDA's approval of VP-102 for the treatment of molluscum by about 3-4 months based on Company estimates.

72. Based on the Company's assurances, analysts determined that the CRL was, as analysts from Jeffries noted, a "rather modest setback in the grand scheme of things" and that this "new development to further delay potential approval of Ycanth by up to 3 months." Cowen noted that although another "pause is frustrating/disappointing," its thesis on the Company is not altered given the well-known FDA backlog and manufacturing delays, the hope that the FDA

will close the CMO's deficiencies within thirty business days, and Verrica's FDA Type A meeting request/review would push likely approval into early 2022. Analysts at Jeffries similarly maintained their price target, while analysts from Northland Securities slightly lowered their price target from $19 per share to $18 per share on September 21, 2021, citing the delayed timing on FDA approval.

73. However, analysts from RBC Capital markets lowered their price target for Verrica to $16 per share on September 20, 2021, from the previous price target of $19 per share, citing the developments relating to Verrica's receipt of the second CRL and "new timing and dynamics around a potential launch" of VP-102. H.C. Wainwright analysts lowered their price target to $20 per share on September 22, 2021, from a previous target price of $24 per share.

5. Verrica Announces That The Issues At Sterling "Have Been Successfully Resolved" And That Verrica Will Resubmit Its NDA For VP-102

74. On November 12, 2021, Verrica announced its financial results for the third quarter ended September 30, 2021. As part of this announcement, Verrica headlined its business highlights and recent developments. These highlights focused on the supposed satisfactory resolution of the deficiencies identified by the FDA and the cause for the September 2021 CRL:

- On September 20, 2021, Verrica announced that the U.S. Food and Drug Administration ("FDA") issued a Complete Response Letter ("CRL") regarding its New Drug Application ("NDA") for VP-102 (cantharidin 0.7% Topical Solution) for the treatment of molluscum contagiosum ("molluscum"). According to the CRL, the FDA identified deficiencies at a facility of a contract manufacturing organization ("CMO"), which were not specifically related to the manufacturing of VP-102 but instead raised general quality issues at the facility. The FDA did not identify any clinical, safety or product specific Chemistry, Manufacturing, and Controls ("CMC") deficiencies related to VP-102. Following the CRL, on September 22, 2021 Verrica received a General Advice Letter from the FDA with recommendations to improve YCANTH's user interface.

- On November 5, 2021, Verrica was notified that the inspection of the CMO has been classified as "voluntary action indicated" ("VAI"), is now

> closed and that the VAI classification will not directly negatively impact FDA's assessment of the Company's NDA regarding this CMO. With the satisfactory resolution of the facility inspection, Verrica has engaged the FDA to determine the next steps toward the potential approval of VP-102 for the treatment of molluscum.

75. Defendant White was also quoted in Verrica's November 12, 2021 announcement, stating: "We are pleased that the issues identified at the CMO unrelated to VP-102 have been successfully resolved, enabling us to move toward approval[.]"

76. Less than three weeks later, on November 29, 2021, Verrica announced that it had resubmitted the NDA for VP-102 for the treatment of molluscum. Verrica further explained that "[t]he resubmission is limited to those sections and elements of the NDA that were identified as deficiencies in the Complete Response Letter (CRL) issued by the FDA in September 2021. The resubmission addresses the successful resolution of inspection deficiencies identified at a contract manufacturing organization (CMO) in the CRL[.]"

77. On December 15, 2021, Verrica announced that the FDA accepted its latest NDA resubmission and assigned a PDUFA date of May 24, 2022.

6. Verrica Announces Receipt Of A Third CRL Due To Deficiencies At Sterling

78. On May 24, 2022, after the close of market, Verrica announced that the FDA had again issued a CRL regarding its NDA for VP-102 for the treatment of molluscum. The press release stated, in relevant part:

> The only deficiency listed in the CRL was related to the deficiencies identified at a general reinspection of Sterling Pharmaceuticals Services, LLC (Sterling), the contract manufacturing organization (CMO) that manufactures Verrica's bulk solution drug product. Sterling advised Verrica on May 20, 2022 that it received notice that it is on OAI status. Sterling's OAI classification resulted from a week-long reinspection of the CMO conducted by FDA in February 2022. The reinspection was conducted approximately 90 days after Sterling was originally classified by the Agency as VAI (Voluntary Action Indicated) on November 17, 2021. Verrica understood that the VAI classification did not indicate that a reinspection was required.

The CRL did not identify any other deficiencies. Moreover, none of the issues identified by FDA during the reinspection were specific to the manufacturing of VP-102. Additionally, Verrica was informed by the Division that it had completed its review of Verrica's NDA and product label, there were no open questions on the NDA review, and the VP-102 label was ready to be communicated. However, Verrica has been informed that internal FDA policy is preventing the Agency from communicating the label and approving the NDA when a CMO has an unresolved classification status or is placed on OAI status.

"Based on the successful PAI of VP-102 at Sterling and our understanding that the Division was ready to communicate our label, we believe our NDA meets the statutory standards for approval and that any issues at Sterling do not impact the manufacturing, quality, efficacy, or safety of VP-102," commented Ted White, Verrica's President and Chief Executive Officer. "However, we recognize that the Dermatology Division's hands may be tied due to the reinspection issues at Sterling and thank them for their efforts working with us to date." In addition, Mr. White noted that "VP-102 is a non-sterile topical dermatology product that is not systemically absorbed. It is completely solvent based and has been demonstrated to have bactericidal and viricidal properties. By comparison, the observations cited at Sterling which led to its OAI classification status were predominantly related to its distinct sterile operations where higher-risk, sterile ophthalmic products are manufactured by Sterling for, among other distributors, the U.S. government."

For additional quality control and oversight at Sterling, Verrica proactively and responsibly maintains a Person in the Plant policy which requires qualified Verrica personnel be present at Sterling whenever VP-102 is manufactured to ensure Verrica's product is in strict compliance with the validated process and cGMP. In addition, Verrica independently tests the drug product manufactured at Sterling on two separate occasions at Alcami Laboratories (Alcami) after manufacturing at Sterling has been completed. First, the bulk solution is tested by Alcami after it is packaged into ampules. Then, it is tested again by Alcami after the ampules are assembled into finished VP-102 applicators.

The FDA previously issued a CRL for Verrica's NDA for VP-102 on September 16, 2021, citing, in part, a deficiency related to the Agency's general inspection of Sterling; likewise, not specifically related to the manufacturing of VP-102. Following the CRL, the FDA classified Sterling as VAI. The Establishment Inspection Report (EIR) issued on November 17, 2021 in connection with the VAI specifically stated that (i) FDA would not take or recommend regulatory or enforcement action against Sterling, (ii) the VAI classification would not directly negatively impact FDA's assessment of any pending marketing application referencing Sterling, and (iii) approval of an application may depend on a PAI.

Based on the VAI classification of Sterling and the statements contained in the EIR, Verrica was led to believe that any concerns at Sterling had been resolved to FDA's satisfaction, and as specifically required in the CRL for approval of its

> NDA. Accordingly, Verrica resubmitted its NDA on November 24, 2021, which was accepted.
>
> * * *
>
> Mr. White stated that "Verrica is extremely disappointed in the Agency's issuance of the CRL under the totality of these circumstances. However, as Verrica weighs all its options to bring the first FDA-approved treatment for molluscum, one of the largest unmet needs in dermatology, to the market as soon as possible, it will continue to work collaboratively with the Agency." Verrica currently intends to file a Type A meeting request by the end of this week.
>
> In the meantime, Verrica is working collaboratively with Sterling and its regulatory and quality consultants to help Sterling present multiple options to the Agency to allow Sterling to expeditiously satisfy the majority of the deficiencies resulting in its OAI classification and which are the basis for the CRL. Concurrently, Verrica is engaging an additional CMO to serve as an alternative supplier of VP-102's bulk solution.

79. On this news, the Company's shares fell $3.55, or 63.8%, to close at $2.01 per share on May 25, 2022, on unusually heavy trading volume.

80. Analysts from RBC Capital Markets responded to this news by downgrading Verrica to Sector Perform and slashing its price target by 75% to just $4 on May 24, 2022 from a previous price target of $16. In their May 24, 2022 report, RBC noted that "these recurrent offenses highlight the challenges at play with a manufacturing facility that continues to gate regulatory approval. As VRCA is working with FDA and Sterling to expeditiously resolve to the deficiency as well as potentially identify a new CMO partner for the resubmission, we are moving to the sidelines on this new uncertainty and until clarity is afforded on a new path to approval[.]"

81. Analysts at Cowen similarly dropped its price target to $15 from a previous price target of $25 in its May 25, 2022 report, noting that while management indicates the issues with the CMO facility relate to a sterile manufacturing area and VP-102 is manufactured in a non-sterile area without reported deficiencies, "[u]nfortunately, the Agency often does not

differentiate, and although there is the outside chance the CMO will close its sterile manufacturing, management is now qualifying a new manufacturer. As we describe below, that process will likely take nearly a year in terms of qualification, refiling, and approval." Likewise, in its May 31, 2022 analyst report, H.C. Wainwright & Co. commented that "[w]e're encouraged that VP-102, on its own merits, appears to be approvable, but we don't see any obvious shortcuts to approval here given strict FDA CMC hurdles." In response to the delayed launch of VP-102, H.C. Wainwright likewise cut its price target to $12 from a previous price target of $20.

7. After The Class Period, Verrica Replaces Sterling As Its CMO For Its Bulk Solution Manufacturing

82. On June 28, 2022, Verrica announced that the Company held a Type A meeting with the FDA the previous day regarding the path forward for the resubmission and potential approval of the NDA for VP-102 for the treatment of molluscum. In the announcement, Defendant White was quoted as saying: "we are encouraged by the FDA's willingness to work collaboratively with us on the amount of stability data required from an alternative contract manufacturing organization (CMO) for our bulk solution at the time of resubmission[,]" indicating Verrica's intention to transfer its bulk solution manufacturing to a different CMO.

83. On August 11, 2022, in announcing Verrica's second quarter of 2022 financial results, the Company disclosed that Verrica had begun to work with Piramal Pharma Solutions for production of its bulk solution of VP-102. Defendant White was quoted as saying: "Piramal's experience in the commercial manufacturing of liquids combined with the facility's close proximity [Sellersville, Pennsylvania] to Verrica's headquarters will allow our teams to work closely and collaboratively in the technology transfer process." Defendant White further stated in the August 11, 2022 announcement that based on the FDA's feedback and timing of the technology transfer to Piramal, Verrica expected to be able to resubmit the NDA for VP-102 for

the treatment of molluscum in the first quarter of 2023.

84. On January 4, 2023, Verrica announced the "successful completion of the technology transfer of bulk solution manufacturing to Piramal Pharma Solutions." Defendant White was quoted as saying: "Based on our communications with FDA, we believe that the successful tech transfer of bulk solution manufacturing to Piramal will be well-received by FDA and completes a substantial requirement toward the resubmission of our NDA for VP-102 for the treatment of molluscum in the first quarter of 2023."

G. The FDA's Inspections Of Sterling Document Consistent cGMP Violations

85. Sterling is a pharmaceutical contract manufacturer and formulation development company. Sterling mainly manufactures sterile and non-sterile finished OTC human drug products, veterinary drug products, medical devices and homeopathic drugs.

86. From March 22 to April 5, 2018, the FDA conducted an establishment inspection of Sterling, which was classified as VAI (the "2018 Sterling Inspection"). At the conclusion of the 2018 Sterling Inspection, the FDA issued a five-item Form 483, documenting the following inspectional observations:

> 1. There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality and purity they purport or are represented to possess.
>
> 2. Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards, sampling plans and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling and drug products conform to appropriate standards of identity, strength, quality and purity.
>
> 3. Procedures describing the handling of written and oral complaints related to drug products are deficiently written and followed.
>
> 4. Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually at least once a year for evidence of deterioration.

> 5. Deviations from written production and process control procedures are not recorded and justified.

87. In addition to the FDA 483, objectionable conditions were verbally discussed during the 2018 Sterling Inspection, including: (1) Lack of standard operating procedures (frequently referred to as "SOPs") to include data integrity controls for both the laboratory and production environments; (2) no SOP to control use of chemically and/or heat-treated pallets; and (3) lack of defined trending regarding Out of Specifications (OOSs) and/or Out of Trends (OOTs).

88. The FDA conducted its second cGMP inspection of Sterling from May 3 to 14, 2021 (the "May 2021 Sterling Inspection"). This FDA inspection resulted in a four-item Form 483, documenting the following inspectional observations:

> 1. Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and/or followed.
>
> 2. Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.
>
> 3. Written records of investigations into unexplained discrepancies and failures of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.
>
> 4. The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

89. The subsequently issued EIR for the May 2021 Sterling Inspection, signed and dated June 21, 2021, noted that "[m]ajor quality system elements such as CAPAs [corrective and preventive actions], root cause analysis, OOS investigations were issues during the previous inspection and have continued to present during this inspection."

90. The EIR also noted that in addition to the FDA 483, objectionable conditions were verbally discussed during the May 2021 Sterling Inspection, including: (1) lack of data integrity controls for the production environments; (2) lack of/incomplete trending practices; and

(3) various aseptic practices increased risk to the product.

91. As Verrica later announced, it was informed on November 5, 2021 that the May 2021 Sterling Inspection was classified as VAI, and thus was now closed.

92. The FDA conducted a third inspection from February 7 to 18, 2022 (the "February 2022 Sterling Inspection"). This FDA inspection resulted in a four-item Form 483, documenting the following inspectional observations:

> 1. Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.
>
> 2. The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.
>
> 3. There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.
>
> 4. Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

93. As Verrica later announced, it was informed by Sterling on May 20, 2022 that the February 2022 Sterling Inspection was classified as OAI. Then on September 27, 2022, the FDA issued a warning letter to Sterling (the "Sterling Warning Letter").[6] The Sterling Warning Letter stated "your firm has significant violations of CGMP regulations. Your firm's poor manufacturing practices are particularly concerning because many of your products[] … are ophthalmic and directed for use in young children."

94. The Sterling Warning Letter's concluding paragraphs noted that "[s]ignificant findings in this letter demonstrate that your firm does not operate an effective quality system in accord with CGMP. In addition to the lack of effective production operations oversight to ensure

[6] *Available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/sterling-pharmaceutical-services-llc-629019-09272022 (last accessed January 8, 2023).

reliable facilities and equipment, we found your quality unit is not enabled to exercise proper authority and/or has insufficiently implemented its responsibilities."

95. Indeed, throughout the three FDA inspections of Sterling, the FDA observed and documented Sterling repeated failure to have written procedures, to follow such procedures, and/or to document and explain why deviations from written procedures occurred.

H. Defendants Knew About, Or Recklessly Disregarded, The FDA's Inspections Of Sterling And The Impact The Observed cGMP Violations Presented Significant Risks To Obtaining Regulatory Approval

1. Defendants Knew Of The FDA's May 2021 Sterling Inspection And The Resulting Form 483

96. As Defendant White stated in the April 13, 2021 Needham Conference, the FDA indicated that an inspection of Sterling was necessary for approval of Verrica's NDA for VP-102 for the treatment of molluscum. Shortly thereafter, on May 3, 2021, the FDA began its May 2021 Sterling Inspection, which concluded with the FDA issuing to Sterling, and specifically to its CEO, a Form 483.

97. Defendants immediately knew of the May 2021 Sterling Inspection and that the inspection resulted in the issuance of a Form 483. Just prior to the start of the Class Period, Defendant White assured investors and analysts that Defendants would immediately learn of the FDA inspections of Verrica's CMOs and their results by highlighting that Verrica's outside consultants would be on-site during the FDA inspections during the April 13, 2021 Needham Conference. In addition, Verrica's "Person In Plant" policy, explained in Verrica's May 24, 2022 press release, required that qualified Verrica personnel be present at Sterling whenever Sterling was manufactured.

98. Moreover, the FDA provides guidance "on defining, establishing, and documenting manufacturing activities of the parties involved in contract drug manufacturing

subject to current good manufacturing practice (CGMP) requirements."[7] The FDA explains that such an agreement should describe how and when the owner (*i.e.*, Verrica) and the contract facility (*i.e.*, Sterling) will communicate with each other, both verbally and in writing, and identify the appropriate contact personnel. The guidance continues that the agreements should "also cover audits, inspections, and communication of findings[,] specifying:

> The agreement should allow owners to evaluate and audit contract facilities to ensure CGMP compliance for specific operations. This provision should cover both routine quality audits and for-cause audits. The agreement should also set owner and contract facility expectations regarding FDA inspections (pre-approval, routine surveillance, and for-cause) with consideration for the nature of the products to be manufactured and/or services to be provided. ***It should include the parties' agreed-upon provisions for communicating inspection observations and findings, as well as relevant FDA actions and correspondence.***
>
> Because contract facilities often provide services to multiple owners, ***the quality agreement should address when, how, and what information the contractor will report to owners about objectionable conditions observed during inspections and audits of the contract facility.*** (Emphasis added).

99. That Verrica immediately knew of the resulting Form 483 from the May 2021 Sterling Inspection is confirmed by a former employee of Verrica ("FE").[8] According to FE, FE recalled being in a meeting with Chief Commercial Officer, Joe Bonaccorso and all his direct reports, including FE and Williams, when they learned about Sterling's Form 483. FE further recalls that the meeting took place in mid-May 2021, and that it was acknowledged in the meeting that the receipt of the Form 483 meant the launch of VP-102 would be delayed until September 2021. FE further stated that Defendant White was well aware of the receipt of the

[7] *Available at*: https://www.fda.gov/media/86193/download (last accessed Jan. 6, 2023).

[8] FE was employed by Verrica as a marketing director from April 2021 until August 2021. For the majority of FE's employment at Verrica, FE reported to Joe Bonaccorso, Verrica's Chief Commercial Officer, who reported to Defendant White. Towards the end of FE's employment, FE reported to Andrew Williams, Verrica's Managing Director of Marketing, who reported to Bonaccorso. In FE's role, FE was responsible for the marketing message for VP-102.

Form 483, explaining that though FE did not often communicate directly with White, they got along well.

100. Defendants also knew, or were deliberately reckless in not knowing that Sterling's receipt of a Form 483 – FDA documentation of objectionable conditions and practices discovered during an FDA inspection that render the facility out of compliance with cGMP – could affect the approval of their NDA. Verrica admitted as such in its 2021 10-K, as well as its Form 10-K for the year ended December 31, 2020 ("2020 10-K"), which both stated: "[t]he FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements[.]" The 2020 and 2021 10-Ks further stated: "FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use."

2. Defendants Were, At Minimum, Deliberately Reckless In Repeatedly Assuring Investors That The May 2021 Sterling Investigation And The Related Observed Deficiencies Had Been Successfully Resolved

101. After Verrica received its September 2021 CRL it knew that the deficiencies cited during the May 2021 Sterling Inspection were required to have "been resolved to the FDA's satisfaction" for approval of Verrica's NDA. Verrica admitted to this requirement in its May 24, 2022 announcement. Despite Defendants' repeated assurances that the deficiencies cited in the May 2021 Sterling Inspection had been "successfully resolved," they had ***not*** been resolved, as evidenced by the FDA issuing Form 483 at the conclusion of the February 2022 Sterling Inspection, and classifying the February 2022 Sterling Inspection as OAI, which led to the publication of the Sterling Warning Letter.

102. Defendants explained in Verrica's May 24, 2022 announcement that "[b]ased on the VAI classification of Sterling and the statements contained in the EIR, Verrica was led to

believe that any concerns at Sterling had been resolved to FDA's satisfaction." Verrica included the specific statements from the FDA leading to this belief: "that (i) FDA would not take or recommend regulatory or enforcement action against Sterling, (ii) the VAI classification would not directly negatively impact FDA's assessment of any pending marketing application referencing Sterling, and (iii) approval of an application may depend on a PAI."

103. This language closely tracks with the FDA's readily available sample VAI decisional letter,[9] which states: (i) "A VAI inspection classification indicates that, although investigators found and documented objectionable conditions during the inspection, FDA will not take or recommend regulatory or enforcement action[;]"and (ii) "An inspection classification of VAI for CGMP compliance will not directly negatively impact FDA's assessment of any pending marketing application referencing this facility. Please note, however, that application approval will depend on a product- and application-specific facility assessment conducted by CDER's Office of Pharmaceutical Quality."

104. In fact, Verrica's May 24, 2022 announcement makes clear that it was not the FDA that concluded that its concerns relating to Sterling had been satisfied. Rather, the statements from which Defendants took assurance seem to be standard language used by the FDA when informing a facility of its inspection classification.

105. Moreover, Verrica repeatedly told investors in its September 2021 announcement of the CRL and in its corporate presentation filed with the SEC on Form 8-K on September 29, 2021 that the next step in Verrica's resubmission of its NDA for VP-102 would be to request a Type A meeting with the FDA to address the deficiencies at Sterling. However, it does not appear that such a meeting occurred, as Verrica routinely announced the occurrence of a Type A

[9] *Available at* https://www.fda.gov/media/113124/download (last accessed January 8, 2023).

meeting to investors (*see, e.g.*, ¶¶61, 82).

106. Thus, Verrica's conclusion that the deficiencies were "successfully" resolved were not based on any specific confirmation from the FDA, or even Sterling. Indeed, the similar and repeated observations in each of the three FDA inspections of Sterling highlighted in Section IV.G, *supra*, and the FDA's subsequent Warning Letter to Sterling show that the FDA did not consider Sterling's cGMP violations to be successfully resolved.

3. Defendants Knew, Or Were Deliberately Reckless In Not Knowing, Of The FDA's February 2022 Sterling Inspection And The Resulting Form 483

107. After Verrica received its second CRL due to FDA-identified deficiencies that raised general quality issues at Sterling in September 2021, the resolution of which was "specifically required in the CRL for approval of its NDA," Defendants were on notice that any reinspection of Sterling and the FDA's observation were of critical importance to the approval of Verrica's resubmitted NDA for VP-102. For this reason, as well as the reasons in Section IV.H.1, *supra*, Defendants knew, or were deliberately reckless in not knowing, that the February 2022 Sterling Inspection had taken place, had resulted in the issuance of a Form 483, and that the foregoing presented significant risks to Verrica obtaining regulatory approval of VP-102 for molluscum.

V. DEFENDANTS' MATERIALLY FALSE AND/OR MISLEADING STATEMENTS DURING THE CLASS PERIOD

108. The Class Period begins on May 19, 2021. On that day, Defendants White and Davis participated with others on behalf of Verrica in the RBC Capital Markets Global Healthcare Conference. During the presentation, Defendant White was asked to discuss the pre-approval inspections as part of Verrica's pending NDA for VP-102:

> DAN BUSBY: Okay, great. That's a good overview. With your PDUFA date right around the corner, I know there's been some focus on the FDA inspection

> that's required and whether the agency will be able to get into that facility or two facilities on time. Can you provide us with an update on where you stand in that process? And I know FDA introduced some new inspection-related guidance a couple days ago. Does that affect you at all?
>
> TED WHITE: Well, obviously it's a concern because, to your point, the FDA did put out guidance about the inspections. My concern is the backlog of inspections, they've never really addressed that. ***But we fully anticipate that we'll have our inspections take place according to plan, and we have not been notified otherwise.***

109. Defendant White's statement emphasized in ¶108 was materially false and/or misleading when made and/or omitted to state material facts necessary to make the statements not misleading, because it failed to disclose, among other things, the following adverse facts: (1) that the FDA inspection of one of these two facilities, Sterling, had already taken place; (2) that the FDA's May 2021 Sterling Inspection had resulted in the issuance of a Form 483 to Sterling; and (3) that the foregoing presented significant risks to Verrica obtaining regulatory approval of VP-102 for molluscum.

110. On May 28, 2021, Verrica published a press release announcing the extension of the FDA review period of its NDA for VP-102 for the treatment of molluscum. This press release was also attached as exhibit 99.1 to a Form 8-K filed with the SEC on May 28, 2021 and signed by Defendant Davis. The press release included a quote from Defendant White, who stated, in relevant part: "***Importantly, the FDA has recently completed one of the two pre-approval inspections required for approval.***"

111. On June 2, 2021, Verrica participated in the Jefferies 2021 Virtual Healthcare Conference. During his prepared remarks, Defendant White discussed the NDA for VP-102, stating: "We resubmitted the NDA 5 months later in December of 2020. We received acceptance from the agency in early 2021. We received a PDUFA goal date of June 23 of this year, and now that has been extended by 3 months. So, our new PDUFA goal date is September 23 to give the

agency more time to review data and ***complete one inspection at one of our facilities***."

112. Defendant White's statements emphasized in ¶¶110 and 111 were materially false and/or misleading when made and/or omitted to state material facts necessary to make the statements not misleading, because they failed to disclose, among other things, the following adverse facts: (1) that the FDA's May 2021 Sterling Inspection had resulted in the issuance of a Form 483 to Sterling; and (2) that the foregoing presented significant risks to Verrica obtaining regulatory approval of VP-102 for molluscum.

113. On September 20, 2021, Verrica announced that the FDA had issued a CRL regarding its NDA for VP-102 for the treatment of molluscum. The press release stated, in relevant part: "***At no time prior to the CRL was the Company notified by the FDA of any deficiencies at the CMO*** related specifically to the manufacturing of VP-102 or ***that their general investigation of the facility would have any impact on the Company's NDA***."

114. The statement emphasized above in ¶113 was materially false and/or misleading when made and/or omitted to state material facts necessary to make the statements not misleading, because Defendants knew, or were deliberately reckless in not knowing, prior to the issuance of the September 2021 CRL: (1) that the FDA's May 2021 Sterling Inspection had resulted in the issuance of a Form 483 to Sterling; and (2) that the foregoing presented significant risks to Verrica obtaining regulatory approval of VP-102 for molluscum.

115. On November 12, 2021, Verrica issued a press release announcing its financial results for the third quarter ended September 30, 2021. This press release was also attached as exhibit 99.1 to a Form 8-K filed with the SEC on November 12, 2021 and signed by Defendant Kohler. The press release included a quote from Defendant White, who stated, in relevant part: "We are pleased that the ***issues identified at the CMO unrelated to VP-102 have been***

successfully resolved, enabling us to move toward approval[.]"

116. The November 12, 2021 press release also contained business highlights, including:

- On November 5, 2021, Verrica was notified that the inspection of the CMO has been classified as "voluntary action indicated" ("VAI"), is now closed and that the VAI classification will not directly negatively impact FDA's assessment of the Company's NDA regarding this CMO. ***With the satisfactory resolution of the facility inspection***, Verrica has engaged the FDA to determine the next steps toward the potential approval of VP-102 for the treatment of molluscum.

117. Also on November 12, 2021, Verrica filed its Form 10-Q with the SEC for the period ended September 30, 2021, which was signed by Defendants White and Kohler. Verrica's 10-Q filed on November 12, 2021 stated, in relevant part:

> On November 5, 2021, we were notified that the inspection of the CMO has been classified as "voluntary action indicated", or VAI, is now closed and that the VAI classification will not directly negatively impact FDA's assessment of our NDA regarding this CMO. ***With the satisfactory resolution of the facility inspection***, we have engaged the FDA to determine the next steps towards the potential approval of VP-102 for the treatment of molluscum.

118. On November 29, 2021, Verrica issued a press release announcing that the Company had resubmitted its NDA for VP-102 for the treatment of molluscum. The press release stated, in relevant part: "The resubmission addresses ***the successful resolution of inspection deficiencies identified at a contract manufacturing organization (CMO) in the CRL***."

119. Also on November 29, 2021, Verrica filed a Form 8-K with the SEC, which was signed by Defendant Kohler. The Form 8-K attached as exhibit 99.1 an updated corporate presentation for its website. Slide seven of the presentation addressed the U.S. Regulatory Status of VP-102, and stated in relevant part: "Verrica resubmitted the NDA for VP-102 on November 24, 2021; the resubmission is limited to address ***the successful resolution of inspection***

deficiencies identified at the CMO in the CRL[.]"

120. The emphasized statements attesting to the successful resolution of the CMO's inspection deficiencies made in ¶¶115-119 were materially false and/or misleading when made and/or omitted to state material facts necessary to make the statements not misleading, because they failed to disclose, among other things, the following adverse facts: (1) that the inspection and inspection deficiencies at Sterling had not been successfully resolved; (2) that the FDA required successful resolution of the inspection deficiencies to approve Verrica's NDA for VP-102 for molluscum; and (3) that the foregoing presented significant risks to Verrica obtaining regulatory approval of VP-102 for molluscum.

121. On March 2, 2022, Verrica issued its annual report of financial results for the fiscal year ended December 31, 2021 on SEC Form 10-K, and which was signed by Defendants White and Kohler. Therein, Verrica's 10-K stated three times, twice in Item 1. Business, and again in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations:

> On November 5, 2021, we were notified that the inspection of the CMO that had been classified as "voluntary action indicated", or VAI, is now closed and that the VAI classification would not directly negatively impact FDA's assessment of our NDA regarding this CMO. ***With the satisfactory resolution of the facility inspection***, we resubmitted the NDA for the approval of VP-102 for the treatment of molluscum on November 29, 2021. The resubmission was limited to those sections and elements of the NDA that were identified as deficiencies in the CRL issued by the FDA in September 2021. ***The resubmission addressed the successful resolution of inspection deficiencies identified at the CMO in the CRL***, as well as the recommendations included in the General Advice Letter received from the FDA that relate to VP-102's user interface. On December 15, 2021 the FDA accepted our NDA resubmission for VP-102 and assigned a new PDUFA date of May 24, 2022.

122. The emphasized statements attesting to the successful resolution of the CMO's inspection deficiencies made in ¶121 were materially false and/or misleading when made and/or omitted to state material facts necessary to make the statements not misleading, because they

failed to disclose, among other things, the following adverse facts: (1) that the inspection and inspection deficiencies at Sterling had not been successfully resolved; (2) that the FDA required successful resolution of the inspection deficiencies to approve Verrica's NDA for VP-102 for molluscum; (3) that the FDA had recently conducted the February 2022 Sterling Investigation; (4) that the February 2022 Sterling Investigation had resulted in the issuance of a Form 483 to Sterling; and (5) that the foregoing presented significant risks to Verrica obtaining regulatory approval of VP-102 for molluscum.

123. On March 9, 2022, Defendant White presented during the Cowen 42nd Annual Health Care Conference. At the beginning of his presentation, Defendant White was asked about the upcoming May 2022 PDUFA date for the NDA for VP-102, and the level of confidence as the PDUFA date approached. Defendant White responded, in relevant part:

> [W]hile I cannot comment specifically on the NDA, I remain confident that we have a path forward for YCANTH as a potential treatment for molluscum contagiosum. I will tell you that we've had a very consistent and very productive communication with the FDA and we'll continue to work with the FDA toward an approval of YCANTH on or before our May PDUFA date, May 24 PDUFA date.

124. On April 14, 2022, Defendant White presented during the 21st Annual Needham Virtual Healthcare Conference. During the conference, Defendant White was asked to walk through some of the CRLs Verrica had received, and how the Company has been able to address them. Defendant White responded, in relevant part:

> And then the second CRL was totally unrelated to VP-102/Ycanth altogether. This was at one of our contract manufacturers Sterling Pharmaceutical Services in Dupo Illinois. They had just gone through a general inspection from the agency. They had 483 observations that had not been addressed at the time when they were doing our review.
>
> Now, the 483 that the manufacturer received were all on the aseptic sterile side.… Our product is not sterile and wasn't even on the same side of the building. So that was the second CRL. And what we've done, just to ensure that everything is ready to go. We hired Jeff Yuen & Associates who is a former FDA inspector, as well as Greenleaf. And we had them go out go out and do mock inspections at all

of our CMO facilities to ensure that all our CMOs were inspection ready.

125. The Needham analyst then asked Defendant White if, given the upcoming PDUFA date, and that "given that in the last review cycle, like you said the CRL issues were minor and not really associated with the actual product, I guess we should feel pretty confident that we should see an approval here in late May?" Defendant White responded: "From your lips to God's ears. Yes, I am very optimistic."

126. The statements by Defendant White during the analyst conference in ¶¶123-125 omitted to state material facts necessary to make the statements not misleading, because they failed to disclose, among other things, the following adverse facts: (1) that the inspection and inspection deficiencies at Sterling had not been successfully resolved; (2) that the FDA required successful resolution of the inspection deficiencies to approve Verrica's NDA for VP-102 for molluscum; (3) that the FDA had recently conducted the February 2022 Sterling Investigation; (4) that the February 2022 Sterling Investigation had resulted in the issuance of a Form 483 to Sterling; and (5) that the foregoing presented significant risks to Verrica obtaining regulatory approval of VP-102 for molluscum.

127. On May 9, 2022, Verrica filed its Form 10-Q with the SEC for the period ended March 31, 2022, which was signed by Defendants White and Kohler. Verrica's 10-Q filed on May 9, 2022 stated, in relevant part:

> On November 5, 2021, we were notified that the inspection of the CMO has been classified as "voluntary action indicated", or VAI, is now closed and that the VAI classification will not directly negatively impact FDA's assessment of our NDA regarding this CMO. ***With the satisfactory resolution of the facility inspection***, we resubmitted the NDA for the approval of VP-102 for the treatment of molluscum on November 29, 2021. The resubmission was limited to those sections and elements of the NDA that were identified as deficiencies in the CRL issued by the FDA in September 2021. On December 15, 2021 the FDA accepted our NDA resubmission for VP-102 and assigned a new PDUFA goal date of May 24, 2022.

128. The emphasized statement attesting to the successful resolution of the CMO's inspection deficiencies made in ¶127 was materially false and/or misleading when made and/or omitted to state material facts necessary to make the statements not misleading, because they failed to disclose, among other things, the following adverse facts: (1) that the inspection and inspection deficiencies at Sterling had not been successfully resolved; (2) that the FDA required successful resolution of the inspection deficiencies to approve Verrica's NDA for VP-102 for molluscum; (3) that the FDA had recently conducted the February 2022 Sterling Investigation; (4) that the February 2022 Sterling Investigation had resulted in the issuance of a Form 483 to Sterling; and (5) that the foregoing presented significant risks to Verrica obtaining regulatory approval of VP-102 for molluscum.

VI. LOSS CAUSATION

129. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

130. During the Class Period, Plaintiff and the Class purchased Verrica securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

131. Artificial inflation in Verrica's stock price was removed when concealed risks partially materialized and/or the truth about the material misrepresentations and omissions was partially revealed to the public on September 20, 2021 and May 24, 2022. As a direct result of these partial disclosures, the price of Verrica's publicly traded securities declined precipitously on heavy trading volume, causing economic injury to Plaintiff and other members of the Class.

132. On September 20, 2021, after the close of the market, Verrica announced that, on

September 17, 2021, it had received a CRL from the FDA regarding the Company's NDA for VP-102 for the treatment of molluscum. In this announcement, Verrica explained that "[a]ccording to the CRL, the FDA has identified deficiencies at a facility of a contract manufacturing organization (CMO), which are not specifically related to the manufacturing of VP-102 but instead raise general quality issues at the facility."

133. Verrica further stated in its September 20, 2021 announcement that "[t]he Company understands from the CMO that it has implemented corrective actions to address the Agency's concerns and the CMO has advised Verrica that it is expecting a satisfactory resolution of the facility's identified deficiencies from the FDA within the next 30 business days."

134. On this news, the Company's share price fell $1.00, or 8.3%, to close at $11.03 per share on September 21, 2021, on unusually heavy trading volume.

135. On May 24, 2022, after the close of market, Verrica announced that the FDA had again issued a CRL regarding its NDA for VP-102 for the treatment of molluscum. Verrica explained that "[t]he only deficiency listed in the CRL was related to the deficiencies identified at a general reinspection of Sterling …, the contract manufacturing organization (CMO) that manufactures Verrica's bulk solution drug product. Sterling advised Verrica on May 20, 2022 that it received notice that it is on OAI status. Sterling's OAI classification resulted from a week-long reinspection of the CMO conducted by FDA in February 2022."

136. Verrica further stated in their May 24, 2022 press release, that the Company was "informed by the Division that it had completed its review of Verrica's NDA and product label, there were no open questions on the NDA review, and the VP-102 label was ready to be communicated. However, Verrica has been informed that internal FDA policy is preventing the Agency from communicating the label and approving the NDA when a CMO has an unresolved

classification status or is placed on OAI status."

137. On this news, the Company's shares fell $3.55, or 63.8%, to close at $2.01 per share on May 25, 2022, on unusually heavy trading volume.

VII. CORPORATE SCIENTER ALLEGATIONS

138. The Company is liable for the acts of the Individual Defendants and its other employees and agents under the doctrine of *respondeat superior* and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment and/or agency.

139. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to the Company under the corporate scienter doctrine, *respondeat superior*, and agency principles.

140. Aside from the scienter of the Individual Defendants, the facts alleged herein raise a strong inference of corporate scienter as to Verrica as an entity. Corporate scienter may be alleged independent of individual defendants where a statement is made or approved by a corporate official sufficiently knowledgeable about the company to know the statement was false or misleading. Here, the statements alleged were made to the investing public regarding the Company's path towards obtaining regulatory approval of its lead product candidate, VP-102—an important topic that would necessarily require approval by appropriate corporate officers.

VIII. CLASS ACTION ALLEGATIONS

141. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that purchased or otherwise acquired Verrica securities between May 19, 2021 and May 24, 2022, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their

immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

142. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Verrica's shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Millions of Verrica shares were traded publicly during the Class Period on the NASDAQ. As of May 2, 2022, Verrica had 27,519,053 shares of common stock outstanding. Record owners and other members of the Class may be identified from records maintained by Verrica or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

143. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

144. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

145. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

a. whether the federal securities laws were violated by Defendants' acts as alleged herein;

b. whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the Verrica's path towards

obtaining regulatory approval of its lead product candidate, VP-102;

c. whether Defendants knew or deliberately disregarded that their statements were false and misleading;

d. whether Defendants engaged in a scheme to defraud investors;

e. whether the price of Verrica securities were artificially inflated because of Defendants' conduct complained of herein; and

f. to what extent the members of the Class have sustained damages and the proper measure of damages.

146. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

IX. APPLICABILITY OF PRESUMPTION OF RELIANCE (FRAUD-ON-THE-MARKET DOCTRINE)

147. The market for Verrica's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Verrica's securities traded at artificially inflated prices during the Class Period. On September 3, 2021, the Company's share price closed at a Class Period high of $13.96 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Verrica's securities and market information relating to Verrica, and have been damaged thereby.

148. During the Class Period, the artificial inflation of Verrica's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the

damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Verrica's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Verrica and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

149. At all relevant times, the market for Verrica's securities was an efficient market for the following reasons, among others:

a. Verrica shares met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

b. As a regulated issuer, Verrica filed periodic public reports with the SEC and/or the NASDAQ;

c. Verrica regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

d. Verrica was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace; and/or

e. The average daily trading volume for Verrica's securities during the Class Period was approximately 99,028 shares with more than 27.5 million shares of stock outstanding as of May 2, 2022 and a market capitalization reaching over $384 million during the Class Period.

150. As a result of the foregoing, the market for Verrica's securities promptly digested current information regarding Verrica from all publicly available sources and reflected such information in Verrica's share price. Under these circumstances, all purchasers of Verrica's securities during the Class Period suffered similar injury through their purchase of Verrica's securities at artificially inflated prices and a presumption of reliance applies.

151. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

X. INAPPLICABILITY OF THE STATUTORY SAFE HARBOR AND BESPEAKS CAUTION DOCTRINE

152. The statutory safe harbor and/or bespeaks caution doctrine applicable to forward-looking statements under certain circumstances do not apply to any of the allegedly false statements pleaded in this Complaint.

153. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

154. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Verrica who knew that the statement was false when made.

XI. CLAIMS FOR RELIEF

FIRST CLAIM

Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Promulgated Thereunder Against Defendant Verrica Pharmaceuticals, Inc. And The Individual Defendants

155. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

156. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Verrica's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each defendant, took the actions set forth herein.

157. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Verrica's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

158. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Verrica's financial well-being and prospects, as specified herein.

159. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Verrica's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Verrica and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

160. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives

and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

161. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Verrica's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

162. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of

Verrica's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired Verrica's securities during the Class Period at artificially high prices and were damaged thereby.

163. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Verrica was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Verrica securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

164. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

165. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM

Violation of Section 20(a) Of The Exchange Act Against The Individual Defendants

166. Plaintiff repeats and re-alleges each and every allegation contained above as if

fully set forth herein.

167. Individual Defendants acted as controlling persons of Verrica within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

168. In particular, Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

169. As set forth above, Verrica and Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(a) declaring the action to be a proper class action pursuant to Fed. R. Civ. P. 23;

(b) awarding compensatory damages in favor of Plaintiff and all other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including attorney's fees and expert fees; and

(d) awarding equitable, injunctive, and other relief as the Court may deem just and proper.

XIII. JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: January 12, 2023

By: */s/ Lee Albert*

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CERTIFICATE OF SERVICE

I hereby certify that on January 12, 2023, I electronically filed a true and correct copy the foregoing document with the Clerk of Court using the CM/ECF system which will send a notice of electronic filing to all counsel of record who have consented to electronic notification.

/s/ Lee Albert
Lee Albert